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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

UNITED STATES OF AMERICA,)	CASE NO. 18-CR-00258 EJD
)	
Plaintiff,)	STIPULATION AND PROPOSED
)	SUPPLEMENTAL PROTECTIVE ORDER
v.)	
)	
ELIZABETH HOLMES and RAMESH)	
"SUNNY" BALWANI,)	
)	
Defendants.)	

The United States of America, by and through ADAM A. REEVES, Attorney for the United States Acting Under Authority Conferred by 28 U.S.C. § 515, and JEFF SCHENK, JOHN C. BOSTIC, and ROBERT S. LEACH, Assistant United States Attorneys for the Northern District of California, and the defendants, ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, and their attorneys, KEVIN DOWNEY and LANCE WADE of Williams & Connolly for HOLMES, and JEFFREY B. COOPERSMITH and STEPHEN A. CAZARES of Davis Wright Tremaine for BALWANI, hereby stipulate and jointly request that the Court issue a supplemental Protective Order in this case as described below.

~~PROPOSED~~ SUPPLEMENTAL PROTECTIVE ORDER RE FDA AND CMS INFORMATION

1 The parties stipulated to, and the Court entered, a Protective Order in this case on or about July
 2 2, 2018 (Docket #28) (“the Original Protective Order”). During the course of its investigation, the
 3 United States has obtained materials from various government agencies, including the Food and Drug
 4 Administration (“FDA”) and the Centers for Medicare & Medicaid Services (“CMS”), and may obtain
 5 additional materials from the foregoing agencies or from other similar government agencies. These
 6 materials may contain information that the government considers confidential corporate information,
 7 trade secrets, Protected Health Information (PHI, as defined in HIPAA), or protected by certain
 8 privileges and doctrines, such as work product and deliberative process. Accordingly, the parties agree
 9 that a Supplemental Protective Order is necessary to govern access to and use of such “Government
 10 Agency Documents,” which shall include any documents produced by the government bearing a bates
 11 number prefix containing “FDA” or “CMS” and bearing the legend “FDA/CMS – CONFIDENTIAL,”
 12 or any other documents the government identifies in writing as Government Agency Documents that are
 13 in need of protection under the terms of this Supplemental Protective Order. Defendants agree to the
 14 designation of documents as protected under this Supplemental Protective Order or the Original
 15 Protective Order for the purpose of facilitating production of documents without delay caused by a need
 16 for a line by line review of documents, and not based on any agreement or concession that any
 17 documents are worthy of such protection.

18 Therefore, the parties stipulate and agree as follows:

19 1. Each reference to “Private Documents” in paragraphs 1 through 4 and 6 of the Original
 20 Protective Order shall apply to Government Agency Documents.

21 ADDITIONAL PROTECTIONS FOR PHI IN CMS DOCUMENTS

22 2. Pursuant to 45 C.F.R. § 164.512 et seq. and for purposes of compliance with the Health
 23 Insurance Portability and Accountability Act of 1996 (HIPAA), and subject to the provisions of this
 24 Protective Order, legal counsel in this case, the employees and agents of each party, and all non-party
 25 Covered Entities, as that term is defined in HIPAA, are expressly and specifically authorized to use or
 26 disclose Protected Health Information (PHI), as that term is defined in HIPAA, in accordance with this
 27 order to:

- a) comply with the discovery obligations and requests made pursuant to the Federal Rules of Criminal Procedure in this case seeking PHI;
- b) request interviews or depositions and interview, depose, or respond in interviews or depositions in which PHI might be disclosed;
- c) prepare briefs and other materials for the Court so long as such materials are treated in accordance with this Protective Order; and
- d) disclose PHI to a party's expert regardless of whether the expert is a consulting or testifying expert.

3. The intent of the additional protections for PHI is to authorize the use and disclosure of PHI in accordance with 45 C.F.R. § 164.512 and the terms of this Protective Order. To the extent that the uses and disclosures of PHI authorized under this Protective Order may be permitted under other provisions of the HIPAA Privacy Rule, such uses and disclosures shall be made pursuant to and in accordance with 45 C.F.R. § 164.512(e). This paragraph shall not be read to authorize uses and disclosures of PHI that are not otherwise authorized under this Protective Order.

4. Pursuant to 5 U.S.C. § 552a(b)(11), this Protective Order authorizes CMS to release Privacy Act-protected information covered by this Protective Order, without the consent of the subject individual.

CERTIFICATIONS AND MISCELLANEOUS

5. Prior to receiving access to any Government Agency Documents, each Defense Team member shall sign a copy of the attached Certification. By signing the Certification, each Defense Team member acknowledges that:

- a) She or he has reviewed the Original Protective Order as well as this Order;
- b) She or he understands the contents of those Orders;
- c) She or he will access and use Government Agency Documents only as permitted by the terms of those Orders; and
- d) She or he understands that failure to abide by those Orders may result in sanctions by this Court and she or he submits to the jurisdiction of the Court for the purpose

1 of enforcing those Orders and imposing any sanctions for their violation.

2 6. Defense counsel will maintain a copy of each signed Certification. The United States
3 shall have no access to these signed copies without further order of the Court.

4 7. Any pleadings that reveal the contents of Government Agency Documents—either by
5 attaching copies of such documents or by referencing their content—shall be filed under seal or redacted
6 to prevent the disclosure of such contents.

7 8. Any disputes concerning this Stipulation and Protective Order shall be resolved by this
8 Court only after defense counsel and counsel for the United States have first conferred and attempted to
9 resolve the dispute.

10 9. Additionally, in the event either defendant seeks to challenge the designation of a
11 document under this Supplemental Protective Order, or obtain a judicial ruling permitting broader
12 disclosure of the contents of such a document, that defendant shall notify government counsel in this
13 case to inquire whether the United States or any interested person or party objects to public disclosure of
14 a specific document. Upon receipt of such notice, government counsel shall determine whether there is
15 any objection to the requested lifting of protections under this Supplemental Protective Order for the
16 identified document. Government counsel shall provide an email response to any such inquiries by
17 defendants promptly, but no later than ten business days after receiving the inquiry, including
18 identification of any requested redactions of the identified document. In the event government counsel
19 fails to respond to such inquiry by defendants within 10 days, relief from the protections of this
20 Supplemental Protective Order for the identified document shall be automatic.

21 10. As this Order does not directly address the use or introduction of Government Agency
22 Documents at trial, the parties agree to meet and confer in advance of trial regarding appropriate
23 procedures to protect sensitive information in such documents. By stipulating to this Supplemental
24 Protective Order, the defendants do not waive any right they may have to petition the Court *ex parte* and
25 *in camera* to challenge or remove the designation of a document under this Supplemental Protective
26 Order, or the Original Protective Order, to facilitate the appropriate use of that document at trial.
27 Conversely, the government does not concede that any such issues should be addressed *ex parte*.

1 11. Counsel for the defendants shall notify CMS of the completion of this case so that the
2 agency can complete its disclosure tracking obligations. Such notification should be sent to
3 DataUseAgreement@cms.hhs.gov and CMS counsel and a copy of this Order should be attached.

4 12. The parties stipulate to this Order without prejudice to their ability to seek to modify the
5 terms of the Order at a future date.

6 DATED: July 16, 2019

Respectfully submitted,

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8 ADAM A. REEVES
Attorney for the United States
9 Acting Under Authority Conferred
10 by 28 U.S.C. § 515

11 /s/_____
JEFF SCHENK
12 JOHN C. BOSTIC
13 ROBERT S. LEACH
Assistant United States Attorneys

14 DATED: July 16, 2019


15
16 /s/_____
17 KEVIN DOWNEY
18 LANCE WADE
Attorneys for Elizabeth Holmes

19 DATED: July 16, 2019

20
21 /s/_____
22 JEFFREY B. COOPERSMITH
23 STEPHEN A. CAZARES
Attorneys for Ramesh "Sunny"
24 Balwani

25 SO ORDERED.

26 DATED: 7/17/2019

27 
HONORABLE EDWARD J. DAVILA
United States District Court Judge

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

UNITED STATES OF AMERICA,)	CASE NO. 18-CR-00258 EJD
)	
Plaintiff,)	CERTIFICATION REGARDING COMPLIANCE
)	WITH PROTECTIVE ORDER
v.)	
)	
ELIZABETH HOLMES and RAMESH)	
"SUNNY" BALWANI,)	
)	
Defendants.)	

The undersigned acknowledges that she or he has received copies of the Original Protective Order (Dkt. No. 28) and the Supplemental Protective Order in the case of UNITED STATES v. ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, CR 18-258-EJD, and has read, understands, and agrees to the terms of both Orders, and hereby submits to the jurisdiction of the United States District Court for the Northern District of California for the purposes of enforcement of the terms and punishment of any violations thereof.

Date: _____

Signature

Printed Name